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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/741,929

12/19/2003

Clarence Nathaniel Ahlem

202.2D6

4810

26551

7590

07/27/2006

HOLLIS-EDEN PHARMACEUTICALS, INC.
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EXAMINER

BADIO, BARBARA P

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/741,929

Applicant(s)

AHLEM ET AL.

Examiner

Barbara P. Badio, Ph.D.

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 32-37 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 32-37 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Application

2. Claims 1-10 and 32-37 are pending in the present application. Claims 1-10 stand withdrawn from further consideration as being drawn to a nonelected invention. Claims 32-37 will be examined according to MPEP § 803.02.

Double Patenting

3. The provisional rejection of claims 32-37 on the ground of nonstatutory obviousness-type double patenting over claims of copending Application No. 10/877,911 is maintained.

Applicant's statement that the provisional rejection be held in abeyance until patentable subject matter is identified is noted.

4. The provisional rejection of claims 32-37 on the ground of nonstatutory obviousness-type double patenting over claims of copending Application No. 10/749,981 is withdrawn.

Claim Rejections - 35 USC § 112

5. The rejection of claims 32-37 under 35 USC 112, second paragraph is withdrawn.

Claim Objections

6. The objection to claim 36 under 37 CFR 1.75(c), as being of improper dependent form, is withdrawn.

Claim Rejections - 35 USC § 102

7. The rejection of claims 32, 33 and 34 under 35 USC 102(b) over Labrie (US 6,432,940) is withdrawn.

8. Claim 32, 33 and 35 are rejected under 35 USC 102 (b) over Saari et al. (US 5,183,815).

Saari et al. teaches novel bone acting agents such as 3 α -(4,4-diphosphonobutylaminocarbonyloxy)-5 α -androstane-17-one (see the entire article, especially col. 1, line 45 – col. 3, line 48; Example 2). The reference teaches the compounds are useful in treating bone disorders such as osteoporosis (see for example Abstract). The method of use taught by the reference is encompassed by the instant claim.

Claim Rejections - 35 USC § 103

9. **The rejection of claims 32-34 and 36 under 35 USC 103(a) over Labrie (US 6,432,940) is withdrawn.**

10. Claims 32, 33 and 35 are rejected under 35 USC 103(a) over Saari et al. (US 5,183,815).

Saari et al. teaches novel bone acting agents such as 3 α -(4,4-diphosphonobutylaminocarbonyloxy)-5 α -androstane-17-one (see the entire article, especially col. 1, line 45 – col. 3, line 48; col. 4, line 61, bolandiol; Example 2). The reference teaches the compounds are useful in treating bone disorders such as osteoporosis (see for example Abstract).

The instant claims differ from the reference by reciting compounds not exemplified by the reference. However, Saari teaches the utilization of any hydroxyl containing steroid hormone possessing human bone resorption antagonist activity or bone formation stimulatory activity (see col. 1, lines 62-64; col. 4, line 59 - col. 6, line 65). Therefore, it would have been obvious to the skilled artisan in the art at the time of the present invention to select any of the species of the genus of the reference, including any 4-ene bone resorption antagonist steroid derivative, with the reasonable expectation that the compound obtained would be useful in the treatment of osteoporosis as taught by Saari et al.

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11. Claims 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arnold (US 5,880,117) in view of Nielsen et al. (US 4,849,220).

Arnold teaches 4-androstenediol, including 4-androstene-3 α ,17 β -diol, as precursor to testosterone (see the entire article, especially col. 2, lines 10-28; claims 1-4). The reference also teaches testosterone is effective in the maintenance of bone mass (see col. 1, lines 8-12).

The instant claims differ from the reference by reciting the treatment of osteoporosis. However, osteoporosis is known in the art to be caused by loss of bone density/mass and the art teaches that decline in hydroxylated steroids, such as testosterone and estradiol, is a cause of osteoporosis (see for example, Nielsen et al, US 4,849,220, especially Abstract). The art also teaches testosterone is a natural precursor of estrogens (references will be provided upon request). Therefore, the skilled artisan in the art at the time of the present invention would have been motivated to utilize 4-androstenediol taught Arnold because he would have the reasonable expectation of increasing the level of testosterone and estrogens, such as estradiol and, thus, the treatment of osteoporosis as taught by Nielsen et al.

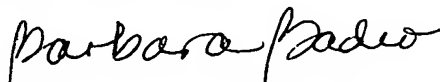
Telephone Inquiry

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1617

BB

July 24, 2006